IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

OHIO CARPENTERS' HEALTH FUND, individually and on behalf of all others similarly situated, Plaintiff, v. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, PHILIPS HOLDING USA INC., PHILIPS RS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA HOLDING CORPORATION, Defendants.	Case No. 2:22-cv-1228 **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff Ohio Carpenters' Health Fund ("Plaintiff" or "Ohio Carpenters"), a third-party payor ("TPP"),[1] individually and on behalf of all others similarly situated, through the undersigned counsel, alleges as follows:

NATURE OF THE ACTION

1. Defendants Koninklijke Philips N.V., Philips North America LLC, Philips Holding USA Inc., Philips RS North America LLC, and Philips RS North America Holding Corporation (collectively, "Philips") manufacture and sell certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and mechanical ventilators ("ventilators"), which treat respiratory failure. In general, these devices blow

[1] The term "third-party payor" or "TPP" refers to any private health insurance companies, third-party administrators, health maintenance organizations, health and welfare plans that make payments for health benefits from their own funds, and other health benefit providers and entities with self-funded plans that contract with a health insurer or administrator to administer their health benefits.

air into patients' airways. CPAP and BiPAP machines are intended for daily use, and ventilators are used continuously when needed.

2. On June 14, 2021, Philips announced a recall of millions of its CPAP and BiPAP machines and ventilators (the "Recall"). Each of these recalled products (referred to herein as a "Recalled Device" or collectively as the "Recalled Devices") contained polyester-based polyurethane ("PE-PUR") foam used by Philips for sound abatement. The PE-PUR foam was provided by, among others, Polymer Technologies, Inc. ("PolyTech"). Despite knowing at least as far back as 2015 that PE-PUR foam would degrade and that this foam should not be used in the Recalled Devices, Philips waited until June 2021 to issue the Recall and notify the public. In its Recall, Philips publicly announced that the PE-PUR foam may break down into particles and be inhaled or ingested, or may emit volatile organic compounds ("VOCs") that may be inhaled, resulting in "serious injury, which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment"[2] (referred to herein as the "Defect"). Philips stated that the potential risks of exposure due to such chemicals include "headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea, vomiting, toxic and carcinogenic effects."[3] Philips' announcement to doctors advised that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."[4]

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[2] Philips Recall Notices dated 6/14/2021 (attached hereto as Exhibit "A"). All attached Exhibits and reference material are incorporated as if fully stated herein.

[3] *Id.*

[4] *Id.*

3. On July 22, 2021, the U.S. Food and Drug Administration ("FDA") confirmed the severity of the problem and classified the Recall as Class I or "the most serious type of recall," meaning use of the Recalled Devices "may cause serious injuries or death."[5]

4. Philips knew about the serious risks caused by the Recalled Devices long before the Recall. According to the FDA, beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the Recalled Devices, including complaints, test reports, information from suppliers, and information from another entity owned by the ultimate parent company of Philips.

5. Philips notified its shareholders about the Defect in the Recalled Devices in late April 2021, but even then, did not initiate the Recall of the dangerously defective machines until June 14, 2021.

6. In fact, Philips apparently timed its Recall to coincide with its launch of a next generation of the affected products, which Philips claims does not suffer from the same defective and harmful foam issues. Thus, at the time of the Recall, the only purportedly safe option that Philips offered to its customers — many of whom require a BiPAP or CPAP machine to sleep safely — was to purchase, ***at full price***, Philips' new, next-generation device, profiting Philips further.

7. Because of the increased demand for safe and effective CPAP, BiPAP, and ventilator devices, replacement machines are difficult to find and expensive, a situation that was exacerbated by a shortage of microchips for these devices. Thus, many users were forced into a Hobson's choice — continue using their Philips' Recalled Devices and expose themselves to risks

[5] https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and (last accessed Aug. 25, 2022).

of serious injury or death or stop using their breathing devices and risk health consequences from their underlying conditions.

8. Philips' flagship line and top seller of its CPAP Recalled Devices are its DreamStation devices. On September 1, 2021, Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States.[6] DreamStation customers, however, were not told when they might receive a replacement device, nor were they given any specifics as to how the replacement program would work. Moreover, the repair and/or replacement process was only for DreamStation Recalled Devices and did not encompass any other Recalled Device.

9. The Recalled Devices are:

- E30;
- DreamStation ASV;
- DreamStation ST, AVAPS;
- SystemOne ASV4;
- C Series ASV, S/T, AVAPs;
- OmniLab Advanced Plus;
- SystemOne (Q Series);
- DreamStation CPAP, Auto CPAP, BiPAP;
- DreamStation Go CPAP, APAP;
- Dorma 400, 500 CPAP;
- REMStar SE Auto CPAP;

[6] https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-and-other-markets (last accessed Aug. 25, 2022).

- Trilogy 100 and 200;
- Garbin Plus, Aeris, LifeVent;
- A-Series BiPAP Hybrid A30;
- A-Series BiPAP V30 Auto;
- A-Series BiPAP A40; and
- A-Series BiPAP A30.

10. All of the Recalled Devices suffer from the same problem, the use of the PE-PUR foam.

11. Plaintiff, a TPP, paid in whole or in part for the cost of Recalled Devices its insured beneficiaries purchased or leased. Plaintiff would not have paid for the Recalled Devices had it known that the PE-PUR foam in the Recalled Devices could expose users to life-threatening injuries or cause serious health problems, rendering the Recalled Devices defective and unsafe, and not fit for their intended purpose.

12. Plaintiff, individually and on behalf of all other similarly situated TPPs that paid, in whole or in part, for the defective Recalled Devices its insured beneficiaries purchased or leased, seeks to recover economic losses and punitive damages from Philips for breach of express warranty, breach of the implied warranty of merchantability, breach of the implied warranty of usability, fraud, unjust enrichment, and applicable statutes.

THE PARTIES

Plaintiff

13. Plaintiff Ohio Carpenters' Health Fund ("Ohio Carpenters") is located in Troy, Michigan. Ohio Carpenters is a tax-exempt IRC Section 501(c)(9) Voluntary Employee Benefit Association. Ohio Carpenters is also a multiemployer, collectively bargained trust fund

established in accordance with LMRA §302(c)(5), 29 U.S.C. §186(c)(5), for the purpose of providing benefits for employees and their beneficiaries. Ohio Carpenters provides healthcare benefits to participants and their eligible dependents (collectively, "Beneficiaries"). Ohio Carpenters' insured Beneficiaries located in at least Alaska, Arizona, Florida, Indiana, Kentucky, Michigan, New Jersey, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and West Virginia purchased Recalled Devices for personal use. Ohio Carpenters paid in whole or in part for the cost of Recalled Devices purchased by its insured Beneficiaries. Ohio Carpenters is ultimately at risk and responsible for reimbursing or paying for Beneficiaries' purchases of medically necessary medical devices, such as the Recalled Devices. Had Philips timely and appropriately disclosed the Defect, that information would have been accessible to prescribing physicians and the general public. Physicians would not have prescribed the Recalled Devices, and Ohio Carpenters would not have incurred costs related to them. Ohio Carpenters seeks full reimbursement of all costs associated with acquiring the Recalled Devices for its insured Beneficiaries and for the replacement costs of Recalled Devices.

Defendants

14. Defendant Koninklijke Philips N.V. ("Royal Philips") is a Dutch multinational company having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of the Philips group of healthcare technology businesses including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries, Philips North America LLC and Philips RS North America LLC.[7] As such, Royal Philips controls Philips North

[7] Philips 2020 annual filing with the SEC, n.8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (last accessed Aug. 25, 2022).

America LLC and Philips RS North America LLC with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices.[8]

15. Defendant Philips North America LLC ("Philips NA") is a Delaware company with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips. Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS North America LLC, in North America. The sole member of Philips NA is Philips Holding USA Inc. Philips NA is 100% owned by Philips RS North America Holding Corporation which, in turn, is 100% owned by Philips Holding USA Inc.

16. Defendant Philips Holding USA Inc. ("PHUSA") is a Delaware corporation with its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is 100% owned, directly or indirectly, by Royal Philips. PHUSA owns 100% of Philips RS North America LLC and Philips RS North America Holding Corporation, and is the member/manager of Philips NA.

17. Defendant Philips RS North America LLC ("Philips RS") is a Delaware company with its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[9] Philips RS is 100% owned by Philips RS North America Holding Corporation, which in turn, is 100% owned by PHUSA.

18. Defendant Philips RS North America Holding Corporation ("Philips RS Holding") is a Delaware corporation with its principal place of business at 222 Jacobs Street, Cambridge,

[8] Philips 2020 annual filing with the SEC, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (last accessed Aug. 25, 2022).

[9] Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (last accessed Aug. 25, 2022).

Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, Philips RS Holding is a citizen of Massachusetts and Delaware.

19. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to "Philips" refers to each Philips Defendant individually and collectively.

JURISDICTION AND VENUE

20. The Court has jurisdiction under 28 U.S.C. §1332, as amended by the Class Action Fairness Act of 2005, because the amount and costs, and is a class action in which Plaintiff and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. §1332(d)(2)(A).

21. Venue is proper in this District under 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District.

FACTUAL ALLEGATIONS

A. CPAP and BiPAP Machines and Ventilators Are Prescribed to Treat Breathing Disorders

22. Sleep apnea is a sleeping disorder in which breathing is disturbed during sleep. These disturbances are called "apneas."

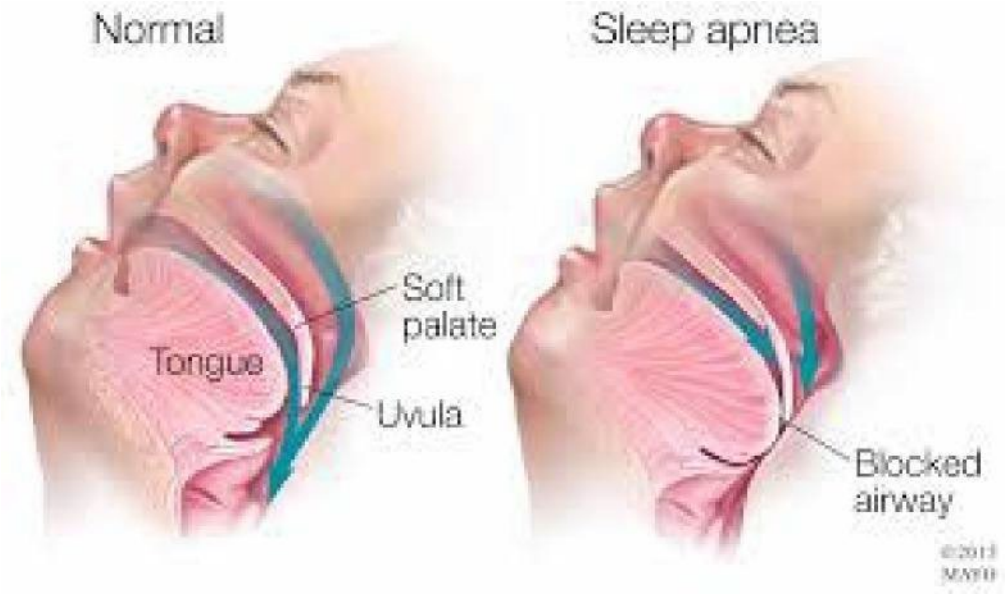
23. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

24. Obstructive sleep apnea is the most common type. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and prevent sufficient air from passing through. This in turn lowers the oxygen level in the blood, which causes the brain briefly to wake the body from sleep to reopen the airway. This reawakening

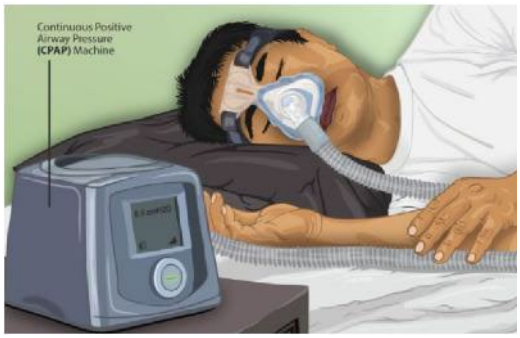
may be so brief that the patient does not remember it, and it may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, and can prevent the patient from reaching the deep, restful phases of sleep.

25. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing, which can cause waking with shortness of breath or difficulty getting to sleep or staying asleep.

26. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea. An image showing how an airway can be blocked as a result of sleep apnea appears below:

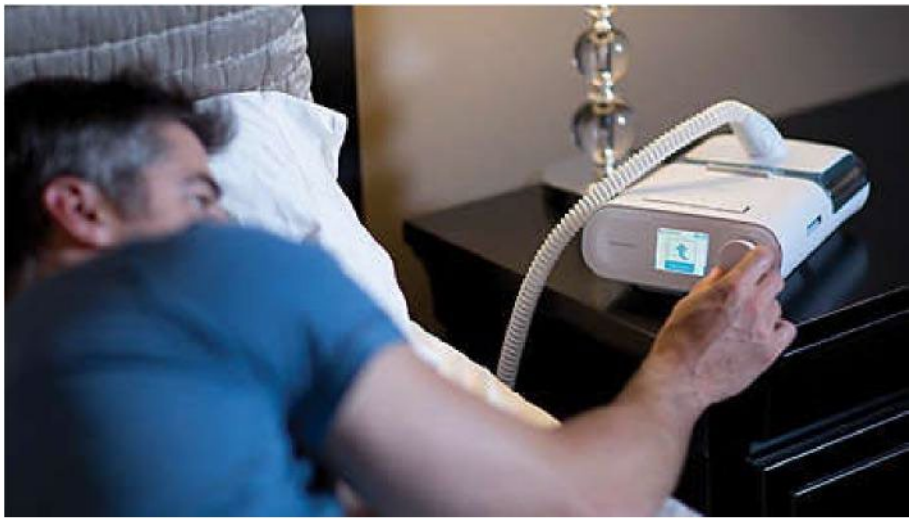


27. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. The illustration below shows a generic CPAP machine being used by a patient while sleeping.



28. Another therapy to treat sleep apnea includes use of BiPAP machines, which use two different pressures – one for inhaling and one for exhaling.

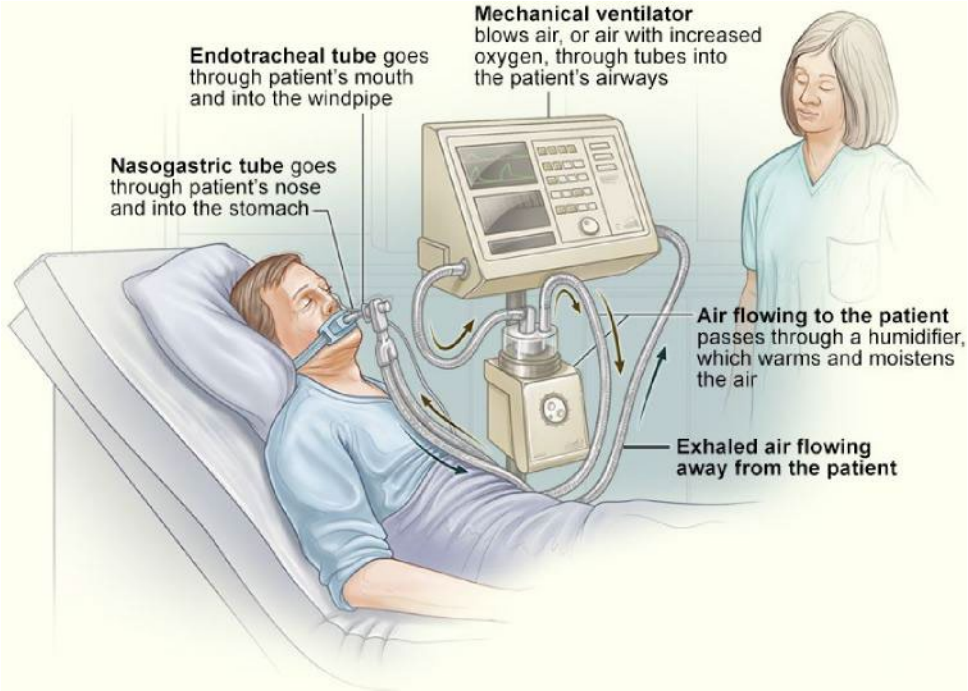
29. Patients customarily place the CPAP or BiPAP machines on a nearby nightstand or shelf. A hose connects the unit to the mask, which is worn over the nose or mouth during sleep. Below is an image of a Philips DreamStation machine on a nightstand.



30. Patients who use CPAP or BiPAP machines typically must use them every time they sleep.

31. Mechanical ventilators, usually called "ventilators," are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows, typically through a tube that is connected to the machine on one end and inserted through the patient's nose or mouth into the trachea on the other end. Patients are typically sedated while on ventilation

because it can otherwise cause intense pain. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. There are also ventilators for home use. The following image from the National Institute of Health shows a typical ventilator and how it works:



B. Philips Sold CPAP, BiPAP, and Ventilator Devices Containing PE-PUR Foam

32. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Philips' 2020 Annual Report,[10] Sleep & Respiratory Care constituted 49% of Philips' total sales in its Connected Care line of business, which in turn accounted for 28% of Philips' overall sales of about €19.535 billion (*i.e.*, $22,541,631,850). Philips has sold millions of CPAP and BiPAP machines and ventilators in the United States.

[10] https://www.results.philips.com/publications/ar20/downloads/pdf/en/PhilipsFullAnnualReport2020-English.pdf?v=20210531142942 (last accessed Aug. 25, 2022).

33. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

34. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

35. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an "arms-race" between manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and quieter.

36. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupt the peaceful sleep of both the patient and their partner, making it less likely that the patient will continue to use the device.

37. Noise is also a problem in neonatal intensive care units where infants, especially those born premature, may remain on ventilators or CPAP or BiPAP devices for long periods.

38. To develop the quietest devices on the market with the lowest decibel ratings, device manufacturers such as Philips filled CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the motor and airflow.

39. Since at least 2009, Philips has incorporated PE-PUR foam in its CPAP, BiPAP, and ventilator devices for sound abatement purposes.

40. In fact, the relative quiet of DreamStation products factored prominently into Philips' marketing.[11] Philips put out information that it extensively studied and measured the amount of sound produced by DreamStation products. Philips even included an infographic indicating DreamStation products are barely louder than a whisper.

41. Polyurethane is an organic polymer in which urethane groups connect the molecular units and is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate as well.

42. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has much better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

43. It has been known for decades that polyester polyurethane is subject to breakdown *via* hydrolysis, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: "Poly(ester urethanes) were the first generation of PURs used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment[.]"[12]

44. Polyether polyurethane, on the other hand, is less prone to breakdown *via* hydrolysis. The same encyclopedia chapter notes that polyether polyurethanes "with excellent

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[11] *See* https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf (last accessed Aug. 25, 2022).

[12] Pal Singh Chauhan, N., and Kumari Jangid, N., "Polyurethanes and Silicone Polyurethane Copolymers," Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, January 2013, available at https://www.researchgate.net/publication/236144965 POLYURETHANES_AND_SILICONE_POLYURETHANE_COPOLYMERS (last accessed Aug. 25, 2022).

hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades."[13]

45. All of the Philips Recalled Devices contain PE-PUR foam.

46. In the DreamStation Recalled Device, for example, there is a channel that surrounds the central fan in the device. The top of this channel is stuffed with PE-PUR foam to absorb the noise from the machine while the patient is sleeping. Air passes through this channel underneath the PE-PUR foam before it enters the fan and is pumped into the patient's airway.

47. There were readily available alternatives available to Philips other than to use PE-PUR foam for sound abatement, including, without limitation, other types of sound abating foam.

48. One of Philips' primary competitors, ResMed, primarily uses polyether polyurethane foam, not PE-PUR foam, for sound dampening.[14]

C. Philips Knew of the Dangers of PE-PUR Foam Since at Least 2015

49. The FDA has concluded that:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.[15]

50. The FDA's finding was based in part on 21 site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator,

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[13] *Id.*

[14] https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Aug. 25, 2022).

[15] https://www.fda.gov/media/158129/download ("518(b) Notice") at 6 (last accessed Aug. 25, 2022).

Katelyn A. Staub-Zamperini, memorialized the agency's finding in a 28-page FDA-483 Report issued on November 9, 2021.[16] The FDA delivered the 483 Report to Rodney Mell, Head of Quality at Philips Respironics, on or around November 9, 2021.[17]

51. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."[18] These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."[19]

52. In connection with its investigation for its 483 Report, the FDA learned that Philips had received numerous complaints from customers in the field about degradation of the foam in its Recalled Devices from at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, ***resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices***. Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that ***30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021***.[20]

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16 A redacted version of the 483 report is available here: https://www.fda.gov/media/154244/download (last accessed Aug. 25, 2022) ("483 Report").

17 *Id*. at 1, 28.

18 https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions (last accessed Aug. 25, 2022).

19 *Id.*

20 483 Report at 12 (emphasis added).

53. Yet, "[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . . ."[21]

54. A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct quality problems when they are detected. *See* 21 C.F.R. §820.100. A CAPA is designed "to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence."[22]

55. The FDA also found that Philips "was made aware of polyester polyurethane foam degradation issues in/around October 2015 . . . ."[23]

56. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Philips knew that a patient discovered "black dust" on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."[24]

57. Philips investigated this report and confirmed that the device contained "evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . . ."[25]

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21 *Id.* at 16.

22 https://www.fda.gov/corrective-and-preventive-actions-capa (last accessed Aug 25, 2022).

23 483 Report at 18.

24 MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, http://www.fdable.com/advanced_maude_query/324fd08a137ce36c2d5faf453ee26f2f (last accessed Aug. 25, 2022).

25 *Id.*

58. Philips, however, stubbornly denied that the presence of the black substance was due to a product defect.

59. The FDA found that Philips' analysis of consumer complaints was itself defective in that it "was not adequately performed to identify or detect quality problems."[26] The FDA concluded that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions."[27] In light of this, the FDA concluded that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.[28]

60. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §360h(b) (the "518(b) Notice").[29] The 518(b) Notice stated that the FDA's "Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b)" of the FDCA "to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated."[30] This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

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26 483 Report at 16.

27 *Id.* at 13.

28 *Id.* at 3.

29 https://www.fda.gov/media/158129/download (last accessed Aug. 25, 2022).

30 518(b) Notice at 1.

61. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."[31]

62. The 518(b) Notice also stated that "there is sufficient evidence for FDA to determine that there are reasonable grounds to believe that the risk associated with the devices was not caused by the failure of a person other than Philips to exercise due care in the installation, maintenance, repair, or use of the devices at issue" and specifically that "evidence indicates that the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care."[32]

63. The FDA concluded that "patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices[.]"[33]

64. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam."[34]

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31 *Id.* at 2.

32 *Id.*

33 *Id.*

34 *Id.* at 6.

1. In 2015, Philips Communicated with Its Foam Suppliers About the Problem of PE-PUR Foam Degradation

65. The PE-PUR foam that Philips used in its Recalled Devices was manufactured by William T. Burnett & Co. ("Burnett"), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as 100 or 200 feet.

66. Burnett sells its bulk foam to intermediaries, including PolyTech and SoundCoat. PolyTech and SoundCoat cut the foam down to a size suitable for use in a medical device. They then sell the foam to Philips, either directly or through another intermediary, Paramount Die, which may modify the foam further.

67. According to the FDA, "email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware of polyester polyurethane foam degradation issues in/around October 2015, which was later confirmed by [Philips'] foam supplier on 08/05/2016, via email."[35]

68. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler, an employee of Burnett, referencing a concern expressed by one of its customers [Philips] in the Fall of 2015 regarding foam degradation in its medical devices.[36] Mr. Marsh stated: "They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity."[37] Mr. Lawler responded that, under those conditions, he "would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a

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35 483 Report at 18.

36 *See* Email exchange between Bob Marsh at PolyTech and Lee Lawler at Burnett (Affidavit of Lee Lawler, Technical and R&D Manager at Burnett ("Lawler Aff.") Exh. E, filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-7) (attached hereto as Exhibit "B"), at WTB 000056.

37 *Id.*

year."[38] He added that "that is not a good environment for polyester foam. Polyether foam could last years in that environment."[39] Mr. Marsh responded that he would "let them [presumably Philips] know they'd be better off with the ether."[40]

69. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.'"[41] Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

70. According to the FDA, "no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented" other than a limited "preventative maintenance procedure" instituted by a "Philips . . . entity owned by the parent company of Philips Respironics" "to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam."[42] And even then, "Philips did not verify the effectiveness of this measure."[43]

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38 *Id.*

39 *Id.*

40 *Id.*

41 518(b) Notice at 7.

42 *Id.* at 6-7.

43 *Id.* at 8.

71. Philips was alerted to more warning signs as it continued to ask its supplier about the properties of the PE-PUR foam it was continuing to put in medical devices that millions of its customers were breathing through daily.

72. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing "determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that 'polyester urethanes show bad resistance against high humidity in combination with high temperature.'"[44] Additional testing "determined that, compared to PE-PUR foam, another type of foam, polyether urethane, 'show[s] a far better resistance against high humidity at high temperature.'"[45]

73. The 483 Report identified "at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices."[46] It listed the specific analyses and tests, including one which concluded that "contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature."[47]

74. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017.[48] Approximately 80 of these complaints concerned CPAP and BiPAP devices.[49]

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44 *Id.* at 7-8.

45 *Id.* at 8.

46 483 Report at 3.

47 *Id.* at 4.

48 518(b) Notice at 7.

49 *Id.* at 8.

75. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam.

2. Philips Opened an Internal Investigation into Foam Degradation in Mid-2018 that Confirmed PE-PUR Foam Is Prone to Degradation

76. On April 12, 2018, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA INV 0988, "to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken."[50] Philips reported that "[u]nits were returned from the field where the Trilogy Removable Air Path Foam [redacted] and the foam in the Inlet Air Path Assembly [redacted] was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail."[51]

77. On April 20, 2018, Vincent Testa, a Project Mechanical Engineer at Philips, emailed Bonnie Peterson, Project Manager at PolyTech. Mr. Testa stated, "We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction . . . ."[52] PAFS foam is PolyTech's open cell, flexible acoustical grade PE-PUR foam.[53] Mr. Testa at Philips continued: "Recently weve [*sic*] received a few complaints from our customers that the foam is disintegrating . . . . The material sheds and is pulled into the ventilator air path. As you can imagine,

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50 *Id.*

51 483 Report at 14.

52 *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H, filed in MDL 3014, Case No. 2:21-mc-01230-JFC, at Doc. 589-10) (attached hereto as Exhibit "C"), at WTB 000070.

53 https://www.polytechinc.com/products/acoustic-foam (last accessed Aug. 25, 2022).

this is not a good situation for our users."[54] Mr. Testa asked, "what could cause this material to break down."[55]

78. On April 23, 2018, Mr. Marsh from PolyTech forwarded Philips' April 20, 2018 email to Mr. Lawler from Burnett, reporting that "[t]he customer [Philips] is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream."[56]

79. On May 2, 2018, Mr. Marsh added in an email to Mr. Lawler that "Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed."[57] Mr. Marsh asked whether exposure to oxygen, higher temperature, and higher humidity could accelerate deterioration of PE-PUR foam.[58]

80. Mr. Lawler responded that he did "not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present."[59]

81. Mr. Testa from Philips admitted in a follow-up email to Bob Marsh from PolyTech on May 3, 2018, that:

> We [Philips] are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in

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54 *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000070.

55 *Id.*

56 *See* Email from Bob Marsh to Lee Lawler dated 4/23/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000070.

57 *See* Email from Bob Marsh to Lee Lawler dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000069.

58 *Id.*

59 *See* Email from Lee Lawler to Bob Marsh dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000069.

> which they would replace the PAFS [ester-based] foam pieces . . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature.[60]

82. Mr. Testa at Philips asked Bob Marsh from PolyTech the following:

> 1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).
>
> > a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.
>
> 2. At the end of the service life, what is the failure mode of this material?[61]

83. Mr. Marsh again forwarded these questions to Mr. Lawler at Burnett, who responded:

> I am unable to answer Question Number 1. We would not recommend using **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.
>
> Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.[62]

84. Mr. Lawler from Burnett added: "Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement."[63] Mr. Marsh at PolyTech responded that he would pass along the information to Philips and that "[w]e

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60 *See* Email from Vincent Testa to Bob Marsh dated 5/3/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000068-69.

61 *Id.*

62 *See* Email from Lee Lawler to Bob Marsh dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000067-68.

63 *Id.* at WTB 000068.

have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it."[64]

85. On May 23, 2018, Mr. Marsh from PolyTech forwarded to Lee Lawler another question from Mr. Testa at Philips, about the degradation of the foam it was using in its Recalled Devices.[65] Mr. Testa explained that Philips had "sent samples to a local lab for analysis."[66] The local lab concluded that the degradation was a result of cleavage of the bonds in the base polymer, and Mr. Testa stated that "[f]urther investigation concluded that prolonged exposure to high humidity causes the foam to degrade."[67] Mr. Testa noted that "[a]s the foam degrades it breaks down into small particulate" and asked whether the foam "maintain[s] its UL 94 Flame Resistance rating if it is broken down into particulate?"[68]

86. Mr. Lawler replied: "I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material."[69]

87. On June 7, 2018, Mr. Testa at Philips again emailed Mr. Marsh at PolyTech:

> As we continue our investigation of the deterioration of the PAFS foam, a few questions has [*sic*] been posed regarding the material. Can you please reach out to your foam supplier regarding the following.

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64 *See* Email from Bob Marsh at PolyTech to Lee Lawler at Burnett dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000067.

65 *See* Email from Bob Marsh to Lee Lawler dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000066-67.

66 *Id.* at WTB 000066.

67 *Id.* at WTB 000067.

68 *Id.*

69 *See* Email from Lee Lawler to Bob Marsh dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit "C" hereto), at WTB 000066.

> 1. What is the actual composition of the polyurethane-ester foam PAFS-038? (CAS #s/percentages/weight percent/reactive groups etc. any chemistry is very appreciated)
>
> 2. What kind of diisocynate is used in the polyurethane foam synthesis process and how much?
>
> 3. Is diethylene glycol or another polyol utilized in the foam synthesis process?
>
> 4. Have you tested to see if all diisocyanate groups are reacted in your foam or are there unreacted groups even after manufacturing?[70]

88. Mr. Marsh forwarded the questions to Mr. Lawler at Burnett, who asked why Mr. Testa needed this information. Mr. Marsh did not provide a definitive answer but said, "What Vince [Testa] told us is that they are investigating alternatives to polyurethane foam (ester and ether)."[71] Mr. Lawler ultimately did not answer Mr. Testa's questions because they touched on Burnett's confidential, proprietary information.

89. On June 20, 2018, Philips closed CAPA INV 0988.[72] According to the FDA, Philips implemented "a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure."[73] Yet "after CAPA INV 0988, Philips modified its CAPA procedures to include 'requirements to help ensure that CAPAs are fully complete [and] appropriately scoped,' and that 'processing the issue [that was the subject of INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.'"[74]

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70 *See* Email from Vincent Testa to Bob Marsh dated 6/7/2018 (Lawler Aff. Exh. I, filed in MDL 3014, Case 2:21-mc-01230-JFC, at Doc. 589-11) (attached as Exhibit "D" hereto), at WTB 000076-77.

71 *See* Email from Bob Marsh to Lee Lawler dated 6/14/2018 (Lawler Aff. Exh. I) (Exhibit "D" hereto), at WTB 000075.

72 483 Report at 15.

73 518(b) Notice at 8.

74 *Id.*

90. The FDA pointed out that Philips' informal CAPA INV[75] related to these Trilogy devices did "not include, investigate, or examine all of your firm's CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane foam, which is susceptible to degradation."[76] But Philips had acknowledged to the FDA that it had "received approximately eighty complaints related to foam degradation, ***on non-Trilogy ventilator devices***, from 2014 to 2017."[77]

91. The FDA concluded that Philips had not "adequately established" procedures for initiating CAPA procedures.[78] Specifically, the FDA faulted Philips for not initiating a "formal" CAPA after receiving "various complaints alleging foam degradation in Trilogy ventilator devices" and then closing its informal investigation just two months later without "verify[ing] the effectiveness" of the limited "preventative maintenance procedure for Trilogy devices."[79]

92. Philips continued to receive more information that suggested that the PE-PUR foam was prone to degradation. According to the FDA, "[a] follow-up email amongst your firm's [Philips'] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints received . . . ."[80]

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75 The Report explained that Philips' practice at the time was to first open CAPA requests – called "CAPA INVs" – as a precursor to a formal CAPA, but this could only occur if approved by a "CAPA Review Board" or delegate. *See* 483 Report at 14-15.

76 *Id.* at 15.

77 *Id.* at 16 (emphasis added).

78 *Id.* at 14.

79 518(b) Notice at 8.

80 483 Report at 18.

93. Further, "[o]n December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that '[p]olyester polyurethane foam showed clear disintegration after 2 weeks."[81]

94. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR foam.

3. Philips Finally Opened a Formal CAPA in 2019 – but Did Not Initiate a Recall for Two More Years

95. In April 2019, Philips received two complaints that "sound abatement foam 'is degrading and entering the air path[.]'"[82]

96. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.[83]

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81 518(b) Notice at 8.

82 *Id.*

83 *Id.* at 8-9.

97. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern . . . ."[84]

98. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products"[85] – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples ***indicate a potential patient risk***. ***Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure***. Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, ***the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.***[86]

99. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam "presents a significant biological risk to patients," and goes on to state that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."[87]

100. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity" and restated that "the cause of degradation was due to chemical

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84 Report at 7; *see also id.* ("Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.").

85 *Id*. at 8.

86 *Id.* at 7-8 (emphasis added).

87 *Id.* at 8.

breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."[88]

101. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything about it:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.
>
> Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.[89]

102. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its CPAP, BiPAP, and ventilator Recalled Devices. Instead, Philips held itself out as a trusted brand and "global leader in the sleep and respiratory markets."[90] Its branding promises consumers that they will "[b]reath easier, sleep more naturally[.]"[91] Philips further assures consumers that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing enhanced patient comfort," among other things. And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatments for sleep disorders.[92]

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88 518(b) Notice at 10.

89 483 Report at 24.

90 http://www.respironics.com/product_library (last accessed Aug. 25, 2022).

91 *Id.*

92 https://www.usa.philips.com/healthcare/solutions/sleep (last accessed Aug. 25, 2022).

103. Philips boasts that it has the "most prescribed CPAP systems by U.S. sleep physicians."[93] The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

E. Philips Belatedly Recalled Its Defective Devices Containing PE-PUR Foam Due to the Serious Health Hazards that They Cause

1. In April and May 2021, Philips Launched the DreamStation 2 and Tried to Convince Patients to Buy It, Without Initiating a Recall

104. Two months prior to the Recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR foam.

105. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips announced that its previous generation DreamStation products posed serious health risks to users and, in the same release, Philips started trying to convince consumers to purchase its DreamStation 2 device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone,* and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.[94]

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93 *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (last accessed Aug. 25, 2022) (citing 2016 Philips survey).

94 https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last accessed Aug. 25, 2022).

106. Philips' April 26, 2021 statement to investors did not disclose the full extent of its knowledge about the risks posed by the PE-PUR foam and attempted to deflect the blame on factors such as ozone cleaners. The FDA later rejected this notion, concluding that "***the unreasonable risk associated with the products was not caused by the use of ozone cleaning agents, nor did the use of ozone to clean the products constitute a failure to exercise due care.***"[95]

107. Meanwhile, Philips continued to conduct tests that confirmed that its breathing products were defective.

108. For example, on May 17, 2021, Ken Cole from RJ Lee, an industrial forensics analytical laboratory and scientific consulting firm, produced a presentation analyzing the foam in Philips' Trilogy EVO devices. The presentation states that the investigation was "prompted by staff observation of color variance across both current production and previous builds."[96]

109. The analysis involved six samples of foam, two from units built in 2018 and four taken from Philips' current production stock in May 2021.[97] Some of the samples from 2021 showed "differing cell structure" which is an "[i]ndication of poor process control."[98] The 2021 foam had "significant contaminants."[99] The foam was supposed to be ether-based,[100] but testing revealed indications that some of the foam was actually ester-based.[101]

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95 518(b) Notice at 10 (emphasis in original).

96 *See* RJ Lee Analysis Review of Trilogy EVO Foam (Lawler Aff. Exh. A, filed in MDL 3014, Case No. 2:21-mc-01230-JFC, at Doc. 589-3) (attached as Exhibit "E" hereto), at (WTB 000001-03).

97 *Id.* at WTB 000006.

98 *Id*. at WTB 000008.

99 *Id.* at WTB 000009; *see also* WTB 000010 ("Indication of poor process control and/or contamination.").

100 *Id.* at WTB 000002.

101 *Id.* at WTB 000013.

2. In June 2021, Philips Finally Recalled Its Defective Devices

110. Finally, on June 14, 2021, Philips issued a recall notice directed to its customers in the United States, stating:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.[102]

111. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family."[103] Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:
>
> For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.
>
> For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.

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102 Recall Notices (Exhibit "A" hereto).

103 *Id.*

> **Possible health risks**
>
> The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.[104]

112. On the same day as the Recall, Philips provided additional information in an announcement entitled "Clinical information for physicians," that explained that the foam breakdown "may lead to patient harm and impact clinical care." It added the following:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, ***it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.***[105]

113. The announcement detailed two types of hazards from the foam in the devices. First, the announcement described dangers due to foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.

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104 *Id.*

105 Sleep and respiratory care update: Clinical information for physicians: https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 25, 2022) (emphasis added).

> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine
>
> - Toluene Diisocyanate
>
> - Diethylene glycol[106]

114. Millions of purchasers across the United States, including Plaintiff, trusted the Recalled Devices. Philips has now revealed that the PE-PUR foam in their breathing machines degrades and exposes patients to toxic particles and gasses.

115. That the patients using the Recalled Devices were exposed to toxic and poisonous chemicals is not reasonably in dispute. According to the Report on Carcinogens, Fifteenth Edition, by the National Toxicology Program in the United State Department of Health and Human Services,[107] toluene diisocyanatos are reasonably anticipated to be human carcinogens based on sufficient evidence of carcinogenicity from studies in experimental animals. Administration of commercial-grade toluene diisocyanate (analyzed as 85% 2,4 isomer and 15% 2,6 isomer) by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels (hemangioma and hemangiosarcoma) in female mice.

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106 *Id.*

107 https://ntp.niehs.nih.gov/ntp/roc/content/zip15.zip (last accessed Aug. 25, 2022).

116. The Report also notes that toluene diisocyanates are used primarily to manufacture flexible polyurethane foams for use in furniture, bedding, and automotive and airline seats. The foam in Philips' Recalled Devices is flexible polyurethane foam.

117. Toluene diamine ("TDA") is classified by the United States Environmental Protection Agency ("EPA") as a probable human carcinogen. The EPA also determined that acute exposure to TDA can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory problems (*e.g.*, asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.

118. The European Union warns that toluene diisocyanate is "fatal if inhaled"[108] and has concluded that toluene diamine "cannot be considered safe for use" even as a hair dye, let alone breathed into the lungs for many hours each night.[109]

119. Diethylene glycol ("DEG") is a widely used solvent, but there is limited information about its toxicity in humans, despite its historical involvement in mass poisonings around the world. Famously, DEG caused the death of 100 people across 15 states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act in 1938.[110]

120. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier,

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[108] https://echa.europa.eu/substance-information/-/substanceinfo/100.043.369 (last accessed Aug. 25, 2022).

[109] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_093.pdf (last accessed Aug. 25, 2022), at 5.

[110] https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf (last accessed Aug. 25, 2022).

tubing, and mask)." The PE-PUR foam is black, and when it breaks down, it can release black particles.[111]

121. Philips concluded in its Health Hazard Evaluations ("HHEs") regarding the foam-degradation risk that:

> [b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track, a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure.[112]

122. Philips' HHEs note that the harm due to foam degradation

> 'may not be immediately recognizable and may not be something that the customer would/could report,' adding that certain harms 'may not be easily linked to the hazardous situation or device use in general' and that in the case of genetic mutations in particular, 'a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage.'[113]

123. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard**: Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
>
> - Dimethyl Diazine

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111 Sleep and respiratory care update: Clinical information for physicians: https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 25, 2022).

112 518(b) Notice at 3-4.

113 *Id.* at 5.

- Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-[114]

124. Philips admitted that the risks of these VOCs include: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."[115]

125. Corroborating the dangerous nature of the Recalled Devices, on July 22, 2021, the FDA upgraded Philips' recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[116]

126. Also, on June 14, 2021, Philips' main competitor, ResMed, issued "[a] message from ResMed's CEO" to the public regarding the Philips Recall. In this notice, ResMed CEO, Mick Farrell, stated that "ResMed devices are safe to use and are not subject to Philips' recall. ResMed devices use a different material than what Philips uses in their recalled machines."[117]

127. ResMed PAP devices and ventilators use polyether polyurethane or silicone-based foam for sound abatement purposes, not PE-PUR foam.[118]

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[114] Sleep and respiratory care update: Clinical information for physicians: https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (last accessed Aug. 25, 2022).

[115] *Id.*

[116] https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions (last accessed Aug. 25, 2022).

[117] https://www.resmed.com/en-us/healthcare-professional/other-manufacturer-recall-2021/ (last accessed Aug. 25, 2022).

[118] https://www.resmed.com/en-us/other-manufacturer-recall-2021/ (last accessed Aug. 25, 2022).

128. On July 8, 2021, Philips released a global supplemental clinical information document that was based on their own testing of the affected devices, stating that, "According to analysis performed by Philips, the majority of particulates are of a size (>8 µm) . . . Smaller particulates (<1-3 µm) are capable of diffusing into deep lung tissue and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size identified was 2.69 µm."[119] The Environmental Protection Agency (EPA) notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases."[120]

129. The purity of the air coming from a breathing device to a patient is highly important and material to a typical patient. Philips advertises the filtration systems in its devices, for example, noting them on a diagram in its DreamStation Family Brochure.[121] Philips' filtration system, however, does not filter out the particles and VOCs described above.

130. As noted here, Philips has admitted that the Recalled Devices are defective and unsafe. Plaintiff and the Class have suffered injuries as a result of their purchases or leases of the Recalled Devices, including substantial economic losses related to their purchases or leases of the

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[119] Sleep and Respiratory Care update Clinical information (July 8, 2021), accessible at https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf (last accessed Aug. 25, 2022).

[120] https://www.epa.gov/pm-pollution/health-and-environmental-effects-particulate-matter-pm (last accessed Aug. 25, 2022).

[121] https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf?gl=1*1l6jo9f*_ga*MTM1OTI5NDM5Ny4xNjIzODE3MzMz*_ga_2NMXNNS6LE*MTYyNjkxMDEyNC4yMi4xLjE2MjY5MTQyNTkuMjc.&ga=2.220564312.1106063144.1626914226-1359294397.1623817333 (last accessed Aug. 25, 2022).

Recalled Devices and accessories, and replacement machines and accessories, and losses from not being able to use their machines, and other consequential damages.

F. Philips' Ineffective Measures to Recall the Devices

131. Philips' CEO, Frans van Houten, stated in the Recall announcement: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."[122]

132. But Philips' "recall" was a recall in name only and did not effectively provide patients with notice of the risks of the Recalled Devices or with new Philips CPAP, BiPAP, or ventilator devices.

1. Many Patients, Providers, and Others Were Not Notified About the Recall

133. On March 10, 2022, the FDA issued a Notification Order under §518(a) of the FDCA.[123] The Notification Order stated that the "FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Devices."[124]

134. The FDA estimated that, after nine months of the Recall, "approximately 50% of patients and consumers who have purchased or received the Recalled Products (excluding ventilators) within the last five years (the service life of the devices) have registered with Philips

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122 https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last accessed Aug. 25, 2022).

123 https://www.fda.gov/media/156811/download (last accessed Aug. 25, 2022).

124 518(a) Notification Order at 2.

to obtain a replacement device."[125] But it was "unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips."[126]

135. The FDA surveyed 182 consignees to determine whether they had been notified of the Recall and found 28 "who had reported to FDA that they were not aware of the recall."[127] The FDA reported its results to Philips on September 8 and October 29, 2021, and Philips did not respond. On November 22, 2021, Philips stated that it had notified 23 of the 28 consignees of the Recall, but Philips did not "indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall."[128] Moreover, Philips' evidence of notification consisted of delivery confirmation receipts, reflecting that written correspondence was delivered to the consignees. As the FDA explained, "[t]ypically, firms demonstrate the effectiveness of its [sic] recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation."[129]

136. Throughout the Recall, the FDA "on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient" and has expressed concern that "it is

125 *Id.*

126 *Id.*

127 *Id.*

128 *Id.*

129 *Id.* at 3.

likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products."[130]

137. Noting "Philips' failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products," the FDA issued an order under Section 518(a) of the FDCA ordering Philips to "notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products **within the next 45 days**[.]"[131]

2. Philips' Repair/Replacement Program Has Been Extremely Slow

138. Those patients who registered their Recalled Devices with Philips for the Recall did not immediately receive replacement devices and were not told when a replacement device would be provided.

139. As Philips' June 14, 2021 announcement explained:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program,

130 *Id.*

131 *Id.* at 4 (emphasis in original).

> Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.[132]

140. In reality, patients may register their DreamStation Recalled Device with Philips for the Recall, but Philips has not immediately replaced the defective PE-PUR foam in the DreamStation Recalled Devices. Rather, patients have had to wait, sometimes for many months, for Philips to repair or replace their devices, and many patients are still waiting for a replacement device.

141. As of the date of this Complaint — more than one year after the Recall was announced — Philips continues to repair or replace defective DreamStation 1 Recalled Devices. In other words, the Recall remains ongoing.

142. The replacement program for the Trilogy devices has been even slower. Philips has only just begun the rework of affected Trilogy 100/200 devices and Philips projects that the process will take approximately 12-14 months to complete.[133]

143. There is no repair or replacement program for any of the other Recalled Devices recalled by Philips.

144. Due to the design of the Recalled Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Also, the FDA warns:

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[132] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam (last accessed Aug. 25, 2022).

[133] https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/ventilation-news-and-updates (last accessed Aug. 25, 2022).

> Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.[134]

145. As a result, the Recall leaves patients without safe, free options. Instead, patients may simply be forced to buy Philips' next-generation product or a competitor's product — at full price, and indeed, thousands of patients have already done so.

146. Thus, Philips intends to, and is, simply profiting from its so-called "recall" by selling more of its next generation product, the DreamStation 2, to affected patients. It appears that Philips intentionally timed the "recall" to coincide with the launch of the DreamStation 2.

147. The FDA also believes that the Recall is not proceeding quickly enough. It recently stated:

> Based on the status of Philips' recall as of the date of this letter [May 2, 2022], CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips' ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and communicated to Philips, to the extent such improvements are achievable by Philips.[135]

CLASS ALLEGATIONS

148. Plaintiff brings this action individually and as a class action, pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3). Ohio Carpenters seeks certification on behalf of a national class (the "Nationwide TPP Class"), defined as follows:

> **Nationwide TPP Class:** All third party health benefits payors in the United States (including its Territories and the District of Columbia) who (i) have been a party to a contract, issuer of a policy or sponsor of a plan which contract, policy or plan provides medical coverage to natural persons, and (ii) have incurred, pursuant to

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134 https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls (emphasis in original) (last accessed Aug. 25, 2022).

135 518(b) Notice at 13.

such contract, policy or plan, full or partial costs for Recalled Devices, which were purchased for personal use.

149. Ohio Carpenters also seeks certification on behalf of the following subclasses (the "State TPP Subclasses"), defined as follows:

> **State TPP Subclasses:** All third party health benefits payors in Alaska, Arizona, Florida, Indiana, Kentucky, Michigan, New Jersey, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and West Virginia who (i) have been a party to a contract, issuer of a policy or sponsor of a plan which contract, policy or plan provides medical coverage to natural persons, and (ii) have incurred, pursuant to such contract, policy or plan, full or partial costs for Recalled Devices, which were purchased for personal use.

150. Together, the Nationwide Class and the Subclasses shall be collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) assigned to this case.

151. Plaintiff reserves the right to adjust, modify, or narrow the Class prior to class certification.

152. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

153. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Class contains at least millions of individuals who purchased, otherwise acquired, or leased a Recalled Device. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at this time, but the Class members are readily ascertainable and can be identified by Defendants' records and records of third parties, such as durable medical equipment providers.

b. Existence and Predominance of Common Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Defendants were unjustly enriched by the sale of Recalled Devices;

ii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Devices;

iii. Whether the Recalled Devices suffer from a design defect;

iv. Whether Philips violated express or implied warranties in selling the Recalled Devices;

v. Whether Philips' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;

vi. The appropriate nature of class-wide equitable relief;

vii. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class;

viii. The appropriate measure of statutory damages; and

ix. Whether Plaintiff is entitled to punitive damages.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiff's claims are typical of the claims of all members of the Class.

d. Adequacy: Plaintiff is an adequate representative of the Class because its interests do not conflict with the interests of the Class that it seeks to represent; Plaintiff has

retained counsel competent and highly experienced in complex class action litigation; and Plaintiff intends to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and its counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

154. The running of any statute of limitations has been equitably tolled by Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from purchasers, users, and physicians the true risks associated with the Recalled Devices.

155. As a result of Defendants' actions, Plaintiff was unaware, and could not have reasonably known or learned through reasonable diligence, that users had been exposed to the risks and harms set forth here, that those risks and harms were the direct and proximate result of Defendants' acts and omissions, and that the Recalled Devices were worthless.

CAUSES OF ACTION

COUNT I

Breach of Express Warranty
on behalf of the Nationwide TPP Class and State TPP Subclasses

156. Plaintiff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

157. Philips warranted that all of the Recalled Devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."[136]

158. Philips breached its express warranty in connection with the sale and distribution of Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here, rendering them unsuitable and unsafe for personal use.

159. Had Plaintiff and the Class known the Recalled Devices were unsafe for use, they would not have paid for them.

160. Philips has breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

161. To the extent privity may be required, Plaintiff and the Class can establish privity with Philips, or alternatively, Plaintiff can establish that it falls into an exception to a privity requirement. Plaintiff and the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

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[136] *See, e.g.*, Warranty Exemplars: Dreamstation (attached hereto as Exhibit "F-1"), at 29; REMstar SE (attached hereto as Exhibit "F-2"), at 21; Trilogy 100 (attached hereto as Exhibit "F-3"), at 163.

162. Alternatively, Plaintiff and the Class were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

163. Plaintiff is not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for more than a year.

164. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

165. As a direct and proximate result of Philips' breach of its express warranty, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT II

Breach of the Implied Warranty of Merchantability on behalf of the Nationwide TPP Class and State TPP Subclasses

166. Plaintiff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

167. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiff and the Class that the Recalled Devices were of merchantable quality and safe for their ordinary and intended use.

168. Such implied warranty of merchantability, contained in U.C.C. §2-314, has been codified in each state.

169. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here rendering them unsuitable and unsafe for personal use.

170. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth here rendering them unsuitable and unsafe for personal use.

171. Had Plaintiff and the Class known the Recalled Devices were unsafe for use, they would not have paid for them.

172. To the extent privity may be required, Plaintiff and the Class can establish privity with Philips, or alternatively, Plaintiff can establish that it falls into an exception to a privity requirement. Plaintiff and the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

173. Alternatively, Plaintiff and the Class were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

174. Plaintiff is not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for more than a year.

175. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

176. As a direct and proximate result of Philips' breach of the implied warranty of merchantability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT III

Breach of the Implied Warranty of Usability on behalf of the Nationwide TPP Class and State TPP Subclasses

177. Plaintiff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

178. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the provider of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiff and the Class that the Recalled Devices were usable for their ordinary and intended use.

179. Such implied warranty arises under U.C.C. §2-314(3) as adopted in each state.

180. Such implied warranty of usability, contained in U.C.C. §2-314, has been codified in each state.

181. Through usage of trade, manufacturers of prescription drugs and medical devices impliedly warrant that their products are usable for the end consumer.

182. Philips breached the implied warranty of usability in connection with the sale and distribution of the Recalled Devices. At the point of sale, the Recalled Devices while appearing normal — contained defects as set forth herein rendering them unusable.

183. Philips, its agents, and employees knew or should have known that the Recalled Devices suffered (and still suffer) from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

184. Philips' Recall announcement instructed Class members to not use Recalled Devices because of the health risks. This renders the products unusable and thus worthless.

185. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Devices were usable for their ordinary and intended use.

186. To the extent privity may be required, Plaintiff and the Class can establish privity with Philips, or alternatively, Plaintiff can establish that it falls into an exception to a privity requirement. Plaintiff and the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

187. Alternatively, Plaintiff and the Class were foreseeable third-party beneficiaries of Philips sale of the Recalled Devices.

188. Plaintiff is not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for more than a year.

189. Had Plaintiff and Class members known that users would not be able to use their Recalled Devices, they would not have paid for them or would have paid significantly less for them.

190. As a direct and proximate result of Philips' breach of the implied warranty of usability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT IV

Common Law Fraud
on Behalf of the Nationwide Class and All State TPP Subclasses

191. Plaintiff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

192. Philips knew that the Recalled Devices posed serious health risks to users.

193. Philips failed to advise Plaintiff and the Class of the material fact that the Recalled Devices posed serious health risks to users. Philips concealed information regarding the adverse health effects posed by the Recalled Devices from Plaintiff and Class members. Philips misrepresented to Plaintiff and the Class members that the Recalled Devices were safe for use.

194. Philips was under a duty to disclose to Plaintiff and Class members the serious health risks posed to users because: (a) Philips was in a superior position to Plaintiff and the Class members to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior bargaining position to Plaintiff and the Class members in determining whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, and websites; (c) Philips made representations regarding the safety of the Recalled Devices and had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices, once Philips became aware of such serious health risks; (d) Philips knew that the Plaintiff and Class members could not reasonably have been expected to learn or discover the serious health risks posed by use of the Recalled Devices prior to purchasing the Recalled Devices, given the representations, concealed material information, and omissions by Philips in its packaging, labels, advertising, and websites; and (e) Philips has a duty to disclose information related to the health and safety of its products.

195. Philips intentionally, knowingly, and recklessly allowed its packaging, labels, advertisements, promotional materials, and websites to mislead Plaintiff and Class members to believe that the Recalled Devices were safe for use.

196. Philips knew that its omissions, concealment, and representations in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices were false, deceptive, inadequate, and misleading, and that the Recalled Devices contained PE-PUR Foam and thus could cause adverse health effects to users of the Recalled Devices.

197. Philips concealed and misrepresented material information regarding the serious health risks posed to users of the Recalled Devices from Plaintiff and the Class members, by failing

to include material information in its packaging, labels, advertisements, promotional materials, and websites.

198. The information undisclosed and concealed by Philips to Plaintiff, Class members, and users of the devices was material, as a reasonable consumer would find information regarding serious adverse health risks associated with the use of the Recalled Devices important when deciding whether to purchase the Recalled Devices.

199. As a result of such deceptive packaging, labels, advertisements, promotional materials, and websites, Plaintiff and the Class members justifiably and reasonably believed the Recalled Devices were safe for use.

200. Philips intentionally, knowingly, and recklessly made these material omissions and misrepresentations, and concealed material information regarding the adverse health risks associated with the Recalled Devices in its packaging, labels, advertisements, promotional materials, and websites regarding the Recalled Devices to induce Plaintiff and Class members to pay for the Recalled Devices.

201. Plaintiff and Class members relied on Philips' deceptive packaging, labels, advertisements, promotional materials, and websites and purchased and used the Recalled Devices to their detriment. Given the deceptive manner in which Philips advertised, represented, and promoted the Recalled Devices, such reliance by Plaintiff and Class members was reasonable and justified.

202. As a direct and proximate result of Philips' material omissions, misrepresentations, and concealment of material information regarding the adverse health effects to users of the Recalled Devices, Plaintiff and Class members have suffered actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective

evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages.

COUNT V

Unjust Enrichment (in the alternative) on behalf of the Nationwide Class and All State TPP Subclasses

203. Plaintiff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

204. Plaintiff and Class members conferred a tangible and material economic benefit upon Philips by purchasing the Recalled Devices. Plaintiff and Class members would not have paid for the Recalled Devices had they known the true risks of using the Recalled Devices.

205. Philips readily accepted and retained these benefits. Philips profited from the sale of the Recalled Devices to the detriment and expense of Plaintiff and Class members.

206. Philips appreciated these benefits. These benefits were the expected result of Philips acting in its pecuniary interest at the expense of their customers. Philips knew of these benefits because Philips was aware of the defective nature of the Recalled Devices; Philips failed to disclose this knowledge, and thereby misled Plaintiff and Class members regarding the nature and quality of the Recalled Devices while profiting from this deception.

207. Under these circumstances, it would be unjust, inequitable, and unconscionable for Philips to retain the economic benefits it received at the expense of Plaintiff and the Class, including because they were procured as a result of Philips' wrongful conduct alleged above. Failing to require Philips to provide remuneration under these circumstances would result in Philips being unjustly enriched at the expense of Plaintiff and Class members who endure being

exposed to the risk of developing serious medical conditions and can no longer use their machines safely.

208. Philips' retention of the benefits conferred upon it by Plaintiff and the Class would be unjust and inequitable.

209. Plaintiff is entitled to restitution of the benefits Philips unjustly retained and/or any amounts necessary to return Plaintiff to the position it occupied prior to dealing with Philips, such amounts to be determined at trial.

210. Plaintiff pleads this claim separately as well as in the alternative to its other claims, as without such claims it would have no adequate legal remedy.

211. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT VI

Alaska Unfair Trade Practices and Consumer Protection Act
Alaska Stat. §§45.50.471, *et seq.*
on Behalf of the Alaska TPP Subclass

212. Plaintiff realleges and incorporates by reference all preceding allegations as though fully set forth herein.

213. Plaintiff brings this cause of action individually and on behalf of the members of the Alaska TPP Subclass.

214. The Alaska Unfair Trade Practices and Consumer Protection Act ("AUTPCPA") was created to protect Alaska consumers from deceptive and unfair business practices.

215. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce and thus is unlawful under Alaska Stat. §45.50.471(a).

216. Plaintiff and Alaska TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes, and suffered ascertainable losses of money

or property as the result of the use or employment of a method, act, or practice declared unlawful by Alaska Stat. §45.50.471(b). Plaintiff and Alaska Subclass members acted reasonably under the circumstances, and Philips' conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

217. Accordingly, pursuant to Alaska Stat. §45.50.531(a), Plaintiff and Alaska Subclass members are entitled to recover either: (1) three times their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages; or (2) $500, whichever is greater. In addition, Plaintiff and Alaska Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

218. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for more than a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, other plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT VII
Arizona Consumer Fraud Act
Ariz. Rev. Stat. §§44-1521, *et seq.*
on Behalf of the Arizona TPP Subclass

219. Plaintiff incorporates by reference all preceding paragraphs.

220. Plaintiff brings this cause of action individually and on behalf of the members of the Arizona TPP Subclass.

221. The Arizona Consumer Fraud Act was created to protect Arizona consumers from deceptive and unfair business practices.

222. Philips' conduct described herein constitutes the act, use, or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Arizona, making it unlawful under Ariz. Rev. Stat. §44-1522(A).

223. Plaintiff and Arizona TPP Subclass members paid for the Recalled Devices on behalf of insureds who purchased them for personal purposes, and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Ariz. Rev. Stat. §44-1522(A). Plaintiff and Arizona TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

224. Accordingly, pursuant to Ariz. Rev. Stat. §44-1528(A), Plaintiff and Arizona TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Arizona TPP Subclass members are entitled to all available

statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT VIII
Florida Deceptive and Unfair Trade Practices Act
Fla. Stat. Ann. §§501.201, *et seq.*
on Behalf of the Florida TPP Subclass

225. Plaintiff incorporates by reference all preceding paragraphs.

226. Plaintiff brings this cause of action individually and on behalf of the members of the Florida TPP Subclass.

227. The Florida Deceptive and Unfair Trade Practices Act was created to protect Florida consumers from deceptive and unfair business practices.

228. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Florida, making it unlawful under Fla. Stat. Ann. §§501.201, *et seq.*

229. Plaintiff and Florida TPP Subclass members relied on the material representations made by Philips and paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Fla. Stat. Ann. §§501.201, *et seq.* Plaintiff and Florida TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

230. Accordingly, pursuant to Fla. Stat. Ann. §§501.201, *et seq.*, Plaintiff and Florida TPP Subclass members are entitled to recover their actual damages, which can be calculated with

a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Florida Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT IX
Florida False Advertising Statute
Fla. Stat. Ann. §§817.06, 817.41, *et seq.*
on Behalf of the Florida TPP Subclass

231. Plaintiff incorporates by reference all preceding paragraphs.

232. Plaintiff brings this cause of action individually and on behalf of the members of the Florida TPP Subclass.

233. The Florida False Advertising Statute was created to protect Florida consumers from deceptive and unfair advertising practices.

234. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice, and the concealment, suppression, and omission of material facts in connection with the advertisement of merchandise, the Recalled Devices, in trade or commerce in Florida and was made with the intention that Plaintiff and Florida TPP Subclass members rely on such advertisements in purchasing the Recalled Devices, making it unlawful under Fla. Stat. Ann. §817.06 and §§817.41, *et seq.*

235. Plaintiff and Florida TPP Subclass members relied on the material representations made by Philips and paid for Recalled Devices of its insureds who purchased them for personal

purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Fla. Stat. Ann. §817.06 and §§817.41, *et seq.* Plaintiff and Florida TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

236. Accordingly, under Fla. Stat. Ann. §817.06 and §§817.41, *et seq.*, Plaintiff and Florida TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Florida TPP Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT X
Indiana Deceptive Consumer Sales Act
Ind. Code §§24-5-0.5-1, *et seq.*
on Behalf of the Indiana TPP Subclass

237. Plaintiff incorporates by reference all preceding paragraphs.

238. Plaintiff brings this cause of action individually and on behalf of the members of the Indiana TPP Subclass.

239. The Indiana Deceptive Consumer Sales Act was created to protect Indiana consumers from deceptive and unfair business practices.

240. Philips' conduct described herein constitutes the knowing use or employment of deception, false promise, misrepresentation, unfair practice, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Indiana, making it unlawful under Ind. Code §§24-5-0.5-1, *et seq.*

241. Plaintiff and Indiana TPP Subclass members paid for Recalled Devices of its insureds who relied on the material representations made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Ind. Code §§24-5-0.5-1, *et seq.* Plaintiff and Indiana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

242. Accordingly, pursuant to Ind. Code §§24-5-0.5-1, *et seq.,* Plaintiff and Indiana TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Indiana Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

243. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for more than a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, other plaintiffs through counsel sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

COUNT XI
Michigan Consumer Protection Act
Mich. Comp. Laws Ann. §§445.901, *et seq.*
on Behalf of the Michigan TPP Subclass

244. Plaintiff incorporates by reference all preceding paragraphs.

245. Plaintiff brings this cause of action individually and on behalf of the members of the Michigan TPP Subclass.

246. The Michigan Consumer Protection Act was created to protect Michigan consumers from deceptive and unfair business practices.

247. Philips' conduct described herein constitutes the act, use, or employment of deception, false promise, misrepresentation, unfair practice, and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Michigan, made with the intention that Plaintiff and Michigan TPP Subclass members would rely upon such conduct in purchasing the Recalled Devices, making it unlawful under Mich. Comp. Law Ann. §§445.901, *et seq.*

248. Plaintiff and the Michigan TPP Subclass members relied upon the material representations made by Philips and paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Mich. Comp. Law Ann. §§445.901, *et seq.*

249. Plaintiff and Michigan TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

250. Accordingly, pursuant to Mich. Comp. Law Ann. §§445.901, *et seq.*, Plaintiff and Michigan TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Michigan TPP Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XII
Ohio Consumer Sales Practices Act
Ohio Rev. Code §§1345.01, *et seq*. ("CSPA")
on Behalf of the Ohio TPP Subclass

251. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of the Complaint.

252. Plaintiff brings this action individually and on behalf of the members of the Ohio TPP Subclass.

253. The Ohio Consumer Sales Practices Act was created to protect Ohio consumers from unfair or deceptive business practices.

254. Philips has intentionally engaged in deceptive and unfair acts or practices, false promises, and misleading and unconscionable commercial practices, including misleading omissions of material fact, in connection with the advertisement, marketing, promotion, and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

255. Plaintiff and Ohio TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Ohio Rev. Code §§1345.02(A); 1345.03(A). Plaintiff and Ohio TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

256. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Ohio TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, Plaintiff and Ohio TPP Subclass members are entitled to cost of suit and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XIII
Ohio Deceptive Sales Practices Act
Ohio Rev. Code §§4165.01, *et seq*. ("ODTPA")
on Behalf of the Ohio TPP Subclass

257. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of the Complaint.

258. Plaintiff brings this action individually and on behalf of the members of the Ohio TPP Subclass.

259. The ODTPA was created to protect Ohio consumers from deceptive business practices.

260. Philips has intentionally engaged in deceptive acts or practices, false promises, and misleading and unconscionable trade practices, including misleading omissions of material fact, in the course of its business, vocation, or occupation in connection with the advertisement, marketing, promotion, and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

261. Plaintiff and Ohio TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful the ODTPA, specifically Ohio Rev. Code §§4165.02(A)(7) and (9), by representing that the Recalled Devices have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have and that the Recalled Devices are of a particular standard, quality, or grade that they do not have. Plaintiff and Ohio TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

262. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Ohio TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, Plaintiff and Ohio TPP Subclass members are entitled to cost of suit and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XIV
Oklahoma Consumer Protection Act
15 Okla. Stat. Ann. §§751, *et seq*. ("OCPA")
on Behalf of the Oklahoma TPP Subclass

263. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of the Complaint.

264. Plaintiff brings this action individually and on behalf of the members of the Oklahoma TPP Subclass.

265. The Oklahoma Consumer Protection Act ("OCPA") was created to protect Oklahoma consumers from unfair methods of competition and unfair or deceptive business practices.

266. Philips has knowingly engaged in deceptive, unconscionable, unlawful, unfair, immoral, unethical, oppressive, unscrupulous, fraudulent, and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion, and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

267. Plaintiff and Oklahoma TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by 15 Okla. Stat. Ann. §§752 (13), 752 (14). Plaintiff and Oklahoma TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

268. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Oklahoma TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Oklahoma TPP Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XV
Pennsylvania Unfair Trade Practices and Consumer Protection Law
73 Pa. Stat. Ann. §§201-1, *et seq*. ("UTPCPL")
on Behalf of the Pennsylvania TPP Subclass

269. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of the Complaint.

270. Plaintiff brings this action individually and on behalf of the members of the Pennsylvania TPP Subclass.

271. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") was created to protect Pennsylvania consumers from fraudulent or deceptive business practices.

272. Philips has knowingly engaged in deceptive, unconscionable, unfair, false, fraudulent, and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion, and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

273. Plaintiff and Pennsylvania TPP Subclass members justifiably relied on Philips' unlawful conduct in paying for the Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the act or practice declared unlawful by 73 Pa. Stat. Ann. §§201-1, *et seq*. Plaintiff and Pennsylvania TPP Subclass members acted as reasonable consumers would have acted under the circumstances and would not have purchased the Recalled Devices had they known the truth.

274. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Pennsylvania TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Pennsylvania TPP Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XVI
South Carolina Unfair Trade Practices Act
S.C. Code Ann. §§39-5-10, *et seq*. ("SCUTPA")
on Behalf of the South Carolina TPP Subclass

275. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs of the Complaint.

276. Plaintiff brings this action individually and on behalf of the members of the South Carolina TPP Subclass.

277. The South Carolina Unfair Trade Practices Act ("SCUTPA") was created to protect South Carolina consumers from unlawful business practices.

278. Philips has knowingly engaged in unlawful, unfair, deceptive, immoral, unethical, oppressive, fraudulent, and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion, and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

279. Plaintiff and South Carolina TPP Subclass members paid for Recalled Devices for its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by S.C. Code Ann. §§39-5-10, *et seq*. Plaintiff and the South Carolina TPP Subclass acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

280. Accordingly, pursuant to the aforementioned statutes, Plaintiff and South Carolina TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those

damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and South Carolina TPP Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary, and all such other relief as the Court deems proper.

COUNT XVII
Tennessee Consumer Protection Act
Tenn. Code Ann. §§47-18-101, *et seq*.
on Behalf of the Tennessee TPP Subclass

281. Plaintiff incorporates by reference all preceding paragraphs.

282. Plaintiff brings this cause of action individually and on behalf of the members of the Tennessee TPP Subclass.

283. The Tennessee Consumer Protection Act ("TCPA") was created to protect Tennessee consumers from deceptive and unfair business practices.

284. Philips' conduct described herein with respect to the Recalled Devices constitutes "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce" in Tennessee, making it unlawful under Tenn. Code Ann. §47-18-104(a).

285. Plaintiff and Tennessee TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Tenn. Code Ann. §47-18-104(b). Plaintiff and Tennessee TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct

would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

286. Accordingly, pursuant to Tenn. Code §47-18-109(a)(1), Plaintiff and Tennessee TPP Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiff and Tennessee TPP Subclass members are entitled to recover treble damages for the willful and knowing violation of the TCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XVIII
Truth in Advertising Act (Utah)
Utah Code Ann. §§13-11a-1, *et seq.*
on Behalf of the Utah TPP Subclass

287. Plaintiff incorporates by reference all preceding paragraphs.

288. Plaintiff brings this cause of action individually and on behalf of the members of the Utah TPP Subclass.

289. The Truth in Advertising Act ("TIAA") was created to protect Utah consumers from deceptive and unfair business practices.

290. Philips' conduct described herein related to Recalled Devices constitutes deceptive, misleading, and false advertising practices and forms in the state of Utah and constitutes conduct which created a likelihood of confusion or of misunderstanding, making it unlawful under Utah Code Ann. §§13-11a-1, 13-11a-3(1)(t).

291. Plaintiff and Utah TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Utah Code Ann. §13-11a-3. Plaintiff and Utah TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

292. Accordingly, pursuant to Utah Code Ann. §13-11a-4(2)(b), Plaintiff and Utah TPP Subclass members are entitled to recover either (1) their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices or (2) $2,000 each, whichever is greater. In addition, given the nature of Philips' conduct, Plaintiff and Utah TPP Subclass members are entitled to recover attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XIX
Virginia Consumer Protection Act
Va. Code Ann. §§59.1-196, *et seq.*
on Behalf of the Virginia TPP Subclass

293. Plaintiff incorporates by reference all preceding paragraphs.

294. Plaintiff brings this cause of action individually and on behalf of the members of the Virginia TPP Subclass.

295. The Virginia Consumer Protection Act ("VCPA") was created to protect Virginia consumers from deceptive and unfair business practices.

296. Philips' conduct described herein constitutes a violation of several of the provisions enumerated in Va. Code Ann. §§59.1-200(A)(1)-(60), including but not limited to: misrepresentations as to a product's characteristics; misrepresentations as to a product's standard or style; advertising goods with intent not to sell as advertised; and any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

297. Plaintiff and Virginia TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by Va. Code Ann. §§59.1-200(A)(1)-(60). Plaintiff and Virginia TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

298. Accordingly, pursuant to Va. Code §59.1-204(A), Plaintiff and Virginia TPP Subclass members are entitled to recover either (1) their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence, and those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices or (2) $500 each, whichever is greater. In addition, given the nature of Philips' conduct, Plaintiff and Virginia TPP Subclass members are entitled to recover treble damages (or $1,000 each, whichever is greater) for the willful and knowing violation of the VCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

COUNT XX
West Virginia Consumer Credit Protection Act
W. Va. Code Ann. §§46A-6-101, *et seq.*
on Behalf of the West Virginia TPP Subclass

299. Plaintiff incorporates by reference all preceding paragraphs.

300. Plaintiff brings this cause of action individually and on behalf of the members of the West Virginia TPP Subclass.

301. The West Virginia Consumer Credit Protection Act ("WVCCPA") was created to protect West Virginia consumers from deceptive and unfair business practices.

302. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce in West Virginia, making it unlawful under W. Va. Code Ann. §46A-6-104.

303. Plaintiff and West Virginia TPP Subclass members paid for Recalled Devices of its insureds who purchased them for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act, or practice declared unlawful by W. Va. Code Ann. §46A-6-102(7). Plaintiff and West Virginia TPP Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

304. Accordingly, pursuant to W. Va. Code §46A-6-106(a), Plaintiff and West Virginia TPP Subclass members are entitled to recover either (1) their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence, and those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase ($0.00), or (b) the cost to replace the Recalled Devices or (2) $200 each, whichever is greater. In addition, given the

nature of Philips' conduct, Plaintiff and West Virginia TPP Subclass Members are entitled to recover statutory damages of $1,000 per violation for the knowing and willful violation of the WVCCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

305. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for nearly a year. Further, at a minimum on October 28, 2021, and on May 16, 2022, other plaintiffs in this multidistrict litigation through counsel sent Philips a letter complying with any required pre-suit notification requirements. Philips has failed to remedy its unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Ohio Carpenters requests, individually and on behalf of the Nationwide TPP Class and State TPP Subclasses, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide TPP Class and State TPP Subclasses defined above, and designate Plaintiff as the class and subclass representative as specified above and Plaintiff's counsel as counsel for the Nationwide TPP Class and State TPP Subclasses;

B. award equitable relief, including but not limited to, requiring Philips to provide restitution and disgorgement of profits;

C. award all damages to which Plaintiff and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiff and the Nationwide TPP Class and State TPP Subclasses demand a trial by jury on all issues so triable.

Dated: August 25, 2022

Respectfully submitted,

By: */s/ Kelly K. Iverson*

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